#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

COLEMAN ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP2004/013728

FILED: 2 DECEMBER 2004

U.S. APPLICATION NO: 10/578,290

35 USC §371 DATE: 11 JANUARY 2007

FOR: PHARMACEUTICAL USES OF BISPHOSPHONATES

MS: Amendment

Commissioner for Patents PO Box 1450

Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The asterisked references were cited in the International Search Report and since copies of said references were forwarded by the International Bureau, only copies of the nonasterisked references are enclosed. The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (862) 778-7852

Date: 7/11/07

Attorney for Applicants Reg. No. 48,152

Sheet 1 of 2

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (REV. 7-85) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION

DOCUMENT NUMBER

(Use several sheets if necessary)

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INITIAL AΑ AB AC ΑD ΑE AF AG ΑH ΑI AJ ΑK ΑI

ATTY, DOCKET NO. 33540-US-PCT APPLICATION NO. 10/578,290 APPLICANT COLEMAN ET AL. FILING DATE JANUARY 11, 2007

Group

# CLASS SUBCLASS FILING DATE

## FOREIGN PATENT DOCUMENTS

U.S. PATENT DOCUMENTS

NAME

DATE

|        | DOCUMENT NUMBER | DATE    | OFFICE | CLASS | SUBCLASS | TRAN | SLATION<br>NO |
|--------|-----------------|---------|--------|-------|----------|------|---------------|
| <br>AM | *WO 03/035081   | 5/1/03  | WIPO   |       |          |      |               |
| AN     | *WO 2004/012728 | 2/12/04 | WIPO   |       |          |      |               |
| <br>AO |                 |         |        |       |          |      |               |
| <br>AP |                 |         |        |       |          |      |               |
| <br>AQ |                 |         |        |       |          |      |               |

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

\*Algur et al., "Synergistic cytotoxic effects of zoledronic acid and radiation in human prostate cancer

| EXAMIN | NER | /Marcos Sznaidman/   | DATE CONSIDERED   | 03/06/2008  |
|--------|-----|--|---|---|
|        | AT  | *Kokufu et al., "A case of effective b<br>for bone metastases from breast ca<br>pp. 1425-1428 (2000) | oisphosphonate therapy of sequer<br>ncer!" Gan to Kagaku Ryoho, Car       | tial pamidronate and incadronate ncer & Chemotherapy, Vol. 27(9), |
|        | AS  | *Jagdev et al., "The Bisphosphonate<br>Evidence for Synergy with Paclitaxe                           | e, Zoledronic Acid, Induces Apopt<br>el," British Journal of Cancer, Vol. | osis of Breast Cancer Cells:<br>8(84), pp. 1126-1134 (2001)       |
|        | AR  | and myeloma cell lines," Internation<br>Press US, Vol. 61(2), pp. 535-542 (                          | al Journal of Radiation: Oncology<br>2005)                                | Biology Physics, Pergamon   |

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

/Marcos Sznaidman/

FORM PTO-1449 (REV. 7-85)

(Use several sheets if necessary)

U.S. DEPARTMENT OF COMMERCE

PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION

ATTY, DOCKET NO. 33540-US-PCT APPLICATION NO. 10/578,290 APPLICANT COLEMAN ET AL. FILING DATE JANUARY 11, 2007

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Sheet 2 of 2

#### EXAMINER INITIAL OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| D        | 1646-1651 (1997)  |
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| D        | *Harvey H.A., "Therapeutic use of bisphosphonates in breast cancer: Studies with zoledronic acid," American Journal of Cancer 2003, New Zealand, Vol. 2, No. Suppl., pp. 19-25 (2003)   |
| D        | *Freyer et al., "Palliative hormone therapy, low dose chemotherapy and bisphosphonate in breast cancer patients with bone marrow involvement and pancytopenia; report of pilot experience,<br>European Journal of Internal Medi                   |
| D        | *Neville-Webbe et al., "The combination of zoledronic acid (ZOL) and trail (tumor necrosis factor related apoptosis inducing ligand) has potential synergistic action in breast cancer cells (BCC," Clinical Oncology, Vol. 15 pp. S28-S29 (2003) |
| D        | Magnetto et al., "Additive antitumor activities of taxoids in combination with the bisphosphonate ibandronate against invasion and adhesion of human breast cardinoma cells to bone," Int. J. Cancer, Vol. 83, pp. 263-269 (1999)                 |
| D        | Stearns et al., "Effects of Alendronate and Taxol on PC-3 ML Cell Bone Metastases in SCID Mice."  |
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